

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Satoshi YOSHIDA et al.

Application No.: Not Yet Assigned

Filed: October 11, 2005

National Stage of International Application No.  
PCT/JP2004/005104 under 35 U.S.C. 371, for  
FOLLICLE-STIMULATING HORMONE  
REDUCTION AGENT

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

MAIL STOP PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§1.56 and 1.97(b), applicants bring to the Examiner's attention the documents listed on attached Form PTO/SB/08 and cited in the international search report. With exception of the U.S. patents, copies of the listed documents are attached. Applicants respectfully request that the Examiner consider the documents listed on attached Form PTO/SB/08 and indicate that they were considered by making an appropriate notation on this form. This Information Disclosure Statement is being filed with the above-referenced application.

The following are listed on the accompanying PTO/SB/08 and are in a non-English language:

1. Japanese Patent Publication No. 2000-281584 - An English language abstract of this document is enclosed.

2. Japanese Patent Publication No. 11-116498 - An English language abstract of this document is enclosed.
3. Japanese Patent Publication No. 2813471 - An English language abstract of this document is enclosed.
4. Japanese Patent Publication No. 2003-510344 - An English language abstract of this document is enclosed.
5. KOLB, V. E., "Recent Observations on the Pathobio Chemical Mechanism Inhibiting Reproduction by Infections," Tieraerztliche Umschau, Vol. 51, No. 6, pp. 371-375, (1996) - An English language abstract of this document is enclosed..
6. YANAGIHORI, A. et al., Japanese Journal of Oriental Medicine, Vol. 51, No. 6, p. 205, (2001).
7. KONDO, S., "Dentoteki Seiyaku ni yoru Hyakubyo Shuji (25) Benibana," Vol. 25, No. 10, pp. 56-58, (1997).
8. ATOYAMA, N. et al., "Heikeigo Futei Shusorei ni Okeru Macrophage Activating Chinese Mixed Herbs (MACH) no Men' ekikei Inshi Chosei Sayo to Rinsho Koka," Japanese Journal of Oriental Medicine, Vol. 54, 2 sheets, (2003).
9. NAITOH, Y. et al., "Clinical Effects and Hormonal Changes on the Treatment with Chinese Herb Medicine (HACHIMI-JIOU-GAN) to Infertile Men," Nihon Funin Gakkai Zasshi, Vo. 35, No. 2, pp. 156-162, (1985).

In lieu of a statement of relevance or the translation of the non-English documents, enclosed is an English-language international search report from the Japanese Patent Office in the PCT international application, from which this national

phase U.S. application is derived, citing these documents and setting forth the relevance thereof.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: October 11, 2005

By: 

David W. Hill  
Reg. No. 28,220

Enclosures  
DWH/FPD/sci

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|---|---|----|---|---|--|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO   |   |    |   | <b>JCO9B</b><br>Application Number: Not Yet Assigned<br>Filing Date: October 11, 2005<br>First Named Inventor: Satoshi YOSHIDA et al.<br>Art Unit: Not Yet Assigned<br>Examiner Name: Not Yet Assigned<br>Attorney Docket Number: |  |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Use as many sheets as necessary) |   |    |   |   |  |
| Sheet   | 1 | of | 1 |   |  |

| U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS |                          |  |  |  |   |
|---|--------------------------|--|--|--|---|
| Examiner<br>Initials                                | Cite<br>No. <sup>1</sup> | Document Number                          | Issue or<br>Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|   |                          | Number-Kind Code <sup>2</sup> (if known) |  |  |   |
|   |                          | US-5,882,672                             | 03-16-1999                                 | KOJIMA et al.                                      |   |
|   |                          | US-4,421,746                             | 12-20-1983                                 | KOJIMA et al.                                      |   |
|   |                          | US-4,469,685                             | 09-04-1984                                 | KOJIMA et al.                                      |   |
|   |                          | US-4,456,597                             | 06-26-1984                                 | KOJIMA et al.                                      |   |
|   |                          |  |  |  |   |

**Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004**

| FOREIGN PATENT DOCUMENTS |                          |   |                                |  |  |                          |
|--------------------------|--------------------------|---|--------------------------------|--|--|--------------------------|
| Examiner<br>Initials     | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | Translation <sup>6</sup> |
|                          |                          | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) |                                |  |  |                          |
|                          |                          | JP 2000-281584  | 10-10-2000                     | YOSHIDA et al.                                     |  | ABSTRACT                 |
|                          |                          | JP 11-116498  | 04-27-1999                     | YOSHIDA et al.                                     |  | ABSTRACT                 |
|                          |                          | JP 2813471  | 08-07-1998                     | KOJIMA et al.                                      |  | ABSTRACT                 |
|                          |                          | JP 2003-510344  | 03-18-2003                     | LEVINSON et al.                                    |  | ABSTRACT                 |

| NON PATENT LITERATURE DOCUMENTS |                          |  |                          |
|---------------------------------|--------------------------|--|--------------------------|
| Examiner<br>Initials            | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  | Translation <sup>6</sup> |
|                                 |                          | GRANT, M. H. J. et al., "Effect of Feeding High-Linoleate Safflower Seeds on Reproductive Endocrine Dynamics in Postpartum Bee Females," J. Anim. Sci. Vol. 81, Suppl. 1/J. Dairy Sci., Vol. 86, Suppl. 1, page 12.  |                          |
|                                 |                          | XIA-ZHANGE, L. et al., "A 5-Day Estradiol Therapy, in Amounts Reproducing Concentrations of the Early-Mid Follicular Phase, Prevents the Activation of the Hypothalamo-Pituitary-Adrenal Axis by Interleukin-1 $\alpha$ in the Ovariectomized Rhesus Monkey," J. of neuroendocrinology, Vol. 7, pp. 387-392, (1995). |                          |
|                                 |                          | KOLB, V. E., "Recent Observations on the Pathobio Chemical Mechanism Inhibiting Reproduction by Infections," Tierärztliche Umschau, Vol. 51, No. 6, pp. 371-375, (1996).   | Abstract                 |
|                                 |                          | YANAGIHORI, A. et al., Japanese Journal of Oriental Medicine, Vol. 51, No. 6, p. 205, (2001).  | NO                       |
|                                 |                          | KONDO, S., "Dentoteki Seiyaku ni yoru Hyakubyo Shuji (25) Benibana," Vol. 25, No. 10, pp. 56-58, (1997).   | NO                       |
|                                 |                          | ATOYAMA, N. et al., "Heikeigo Futei Shusorei ni Okeru Macrophage Activating Chinese Mixed Herbs (MACH) no Men' ekikei Inshi Chosei Sayo to Rinsho Koka," Japanese Journal of Oriental Medicine, Vol. 54, 2 sheets, (2003).   | NO                       |
|                                 |                          | NAITOH, Y. et al., "Clinical Effects and Hormonal Changes on the Treatment with Chinese Herb Medicine (HACHIMI-JIOU-GAN) to Infertile Men," Nihon Funin Gakkai Zasshi, Vol. 35, No. 2, pp. 156-162, (1985).  | NO                       |

|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.